

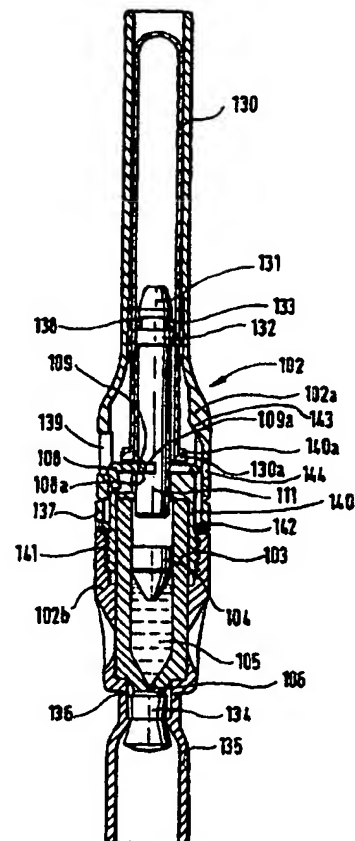


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(21) International Application Number: PCT/GB97/00812 (22) International Filing Date: 21 March 1997 (21.03.97) (30) Priority Data: 9607549.4 11 April 1996 (11.04.96) GB (71) Applicant (for all designated States except US): WESTON MEDICAL LIMITED [GB/GB]; 2a Hales Barn Workshops, New Street, Stradbroke, Eye, Suffolk IP21 5JG (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): WESTON, Terence, Edward [GB/GB]; Thomlea, Pixey Green, Stradbroke, Eye, Suffolk IP21 5NG (GB). (74) Agent: ELKINGTON AND FIFE; Prospect House, 8 Pembroke Road, Sevenoaks, Kent TN13 1XR (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: SPRING-POWERED DISPENSING DEVICE FOR MEDICAL PURPOSES**(57) Abstract**

A dispensing device, such as a needleless injector, comprises a spring, which provides an energy store, and a dispensing member movable, to effect dispensing, under the force of the spring. A latch has a first position in which it restrains movement of the dispensing member and a second position in which it permits such movement. A trigger is operable by the user for moving the latch from the first position to the second position. A safety mechanism, preferably is the form of an appropriately shaped slot in the dispensing member, is effective before the device has been completely assembled to prevent movement of the latch to the second position.



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SPRING-POWERED DISPENSING DEVICE FOR MEDICAL PURPOSES

This invention relates to a dispensing device which engages a spring to urge a dispensing member to disperse, for example, a dose of liquid, powder, or a pellet. The spring may, for example, be a mechanical spring, such as of metal, or a compressed gas spring, such as of compressed air.

One example of such a dispensing device is a needleless injector. Needleless injectors of various types are described in, inter alia, International Patent Publications Nos. WO 93/03779 and WO 95/03844, which are in the name of the present applicant. The present invention will be described in detail with reference to a needleless injector, but it is to be understood that it applies to other types of spring powered dispensing device also.

In a spring powered needleless injector of the type described in the above International Patent Publications, the spring continuously exerts a force on a dispensing member, prior to use, and restraining means are provided for preventing the dispensing member moving under the force of the spring. The needleless injector is fired by, in effect, moving the injector into a condition in which the restraining means no longer have a restraining effect, thus permitting the dispensing member to move.

There is, however, a potential problem in assembling such devices, in that if the device is to be easily operable by the user, it may be easy, or at least possible, for the device to be accidentally fired during the process of manufacture. This is not only wasteful, but also poses a safety hazard to the personnel involved. It is an object of the present invention to provide means for overcoming this problem.

According to the present invention there is provided a device for dispensing a material or article, which comprises a spring, which provides an energy store, a dispensing member movable, to effect dispensing, under the

force of the spring, latch means having a first position in which it restrains movement of the dispensing member and a second position in which it permits such movement, trigger means operable by the user for moving the latch means from said first position to said second position, and a safety mechanism effective before the device has been completely assembled to prevent movement of the latch means to the second position.

In a preferred embodiment of the invention, described in more detail below, the safety mechanism is incorporated into the latch member, which then has a safety position, in which it cannot be moved to its second position by the trigger means, and a non-safety position, in which it can be so moved.

The invention will now be further described with reference to the accompanying drawings, in which:

Figure 1 is a longitudinal section through an embodiment of a needleless injector according to the

invention, and showing the injector prior to use, and with its latch in its safety position;

Figure 1a shows on a larger scale the latch used in Figure 1; and

Figures 2a, 2b and 2c show diagrammatically part of the embodiment of Figures 1 and 1a, in three successive stages, namely with the latch in its safety position, with the latch in its non-safety position prior to firing, and with the latch in its position during firing.

In the embodiment of Figure 1, the injection force is provided by a compressed gas spring. This is in the form of a cylinder 130 which is closed at its upper end and which contains gas, typically air, under a pressure which is typically in the range 5.5 MPa (800 psi) to 20.7 MPa (3000 psi). The cylinder houses a ram 111. The end of the ram 111 has a frustoconical portion 131 and a flange 132 between which is situated an O-ring seal 133. Prior to use, the ram 111 is held in the illustrated position by a

latch 108 engaging in a groove in the ram, the upper surface of the groove forming a cam surface 109. The latch 108 is shown on a larger scale in Figure 1a. In the position shown in Figure 1 the latch is unable to move leftwards, because it bears against the inner wall of a sleeve 102.

The lower end of the cylinder 130 has an outwardly directed flange 130a, which enables the cylinder to be held by crimping the flange 130a beneath an outwardly directed flange 140a at the upper end of a coupling 140. The sleeve 102 is formed of an upper sleeve portion 102a within which the cylinder is situated, and a lower sleeve portion 102b. The sleeve portion 102b is connected to the coupling by the interengaging screw threads 141 formed on the inner and outer walls of the sleeve portion 102b and coupling 140 respectively.

The injector contains a medicament cartridge 103 which has a piston 104 slidingly and sealingly located therein, in contact with medicament 105. As considered from the upper end of Figure 1, the piston may comprise a cylindrical portion, a larger diameter cylindrical sealing portion, and a frusto-conical portion, for example as seen in Figure 1 of PCT/GB96/00551 referred to below. The cartridge 103 has a discharge orifice 106. The orifice 106 is sealed by a resilient seal 134 which is held in place by a seal carrier 135. The seal carrier 135 is connected to the lower sleeve portion 102b by a frangible joint 136.

As a precaution against accidental firing, a tear-off band 137 is provided as the lower part of the upper sleeve portion 102a. The lower edge of the tear-off band 137 bears against a ring 142 which is bonded to the exterior surface of the coupling 140 or (not shown) formed integrally therewith. The function of the ring is to prevent downward movement of the sleeve portion 102a relative to the coupling 140, for so long as the tear-off band 137 is present. Accordingly, the ring 142 need not extend completely around the periphery of the coupling, and

could be replaced by one or more separate elements.

An annular space 138 is formed in the inside wall of the sleeve 102, where the sleeve is adjacent the cylinder 130, and the space is filled with a damping grease (indicated diagrammatically by a succession of black bands), so that the grease is in intimate contact both with the sleeve 102 and the cylinder 130. It should be noted that although a defined annular space is convenient from the point of view of providing a particular location for the grease, it could be omitted and the grease simply smeared over all or part of the outside of cylinder 130 and/or inside of sleeve 102.

When the embodiment of Figure 1 is to be operated, the user snaps off the seal carrier 135 at the frangible joint 136, which takes the seal 134 with it and exposes the orifice 106. The user then removes the tear-off band 137, and grasping the upper part of the sleeve 102 urges the orifice against the substrate (e.g. the user's own skin) which is to be injected. This moves the upper sleeve portion 102a downwardly, with respect to the lower sleeve portion 102b. This brings aperture 139 in the wall of the upper sleeve portion 102a into alignment with the latch 108, which is thus able to move sideways into the aperture under the influence of the force of the gas within the cylinder 130 acting on the latch via the cam surface 109 formed in the ram 111. The injector is thus caused to fire. As a precaution, in case the latch fails to move under the influence of the cam surface 109, an auxiliary cam surface 143 is provided on the inside of the sleeve portion 102a. The resulting recoil is damped by the damping grease.

By way of example only, the following are typical measurements for the embodiment of Figure 1:

Diametrical clearance between gas cylinder outside diameter and sliding sleeve inside diameter	0.05mm
Area of shear (i.e. cross section of grease) approximately	.375mm ²
Viscosity of grease	2.2 Kilopoise
Momentum of ram at impact	0.06kg.m/s
Mass of sleeve portion 102a	1.3g
Mass of ram	2.5g
Impact gap between ram and piston	4mm
Gas pressure	6.2 MPa
Bore of gas cylinder	5.0 mm

While grease has been discussed as a preferred damping medium, similar results may be obtained by using air or oil damping devices - usually a cylinder and piston combination, i.e. a so-called "dashpot", wherein a fluid substance is caused to flow through a restriction, thereby to resist motion. Other viscous damping devices employ a vane, or a plurality of vanes, spinning in a damping medium, for example air, and these may be used if appropriate to the particular application. The effect and purpose of the damping grease is discussed in more detail in our copending International Application No. PCT/GB96/00551.

It will be appreciated that it is important that needleless injectors, or indeed any injectors with power stored in them, should not be able to fire prematurely. Once the above described device has been assembled this is achieved by the presence of the tear band 137, since until that is removed the device cannot fire. However, there is a potential problem in assembling the device, in that the penultimate component to be assembled is the upper sleeve portion 102a, which carries the tear band 137, (the last component to be assembled is the cartridge 103) and until the sleeve portion 102a is in place accidental firing is possible.

Accidental firing during the assembly process is a real possibility. Firstly, immediately prior to installation of the upper sleeve portion 102a there is a stage in which the partially assembled device has a period

of quarantine to check for gas leaks. Secondly, during installation of the upper sleeve portion 102a the device will be subjected to numerous forces and vibration arising from the assembly equipment. Even after installation of the upper sleeve portion 102a, the assembly stresses arising as the cartridge is installed may be sufficient to cause accidental firing, despite the presence of the tear band 137.

To deal with this problem the device has a safety mechanism. In the illustrated embodiment this is provided by forming the slot in the ram not only with the cam surface 109 but also with a locking surface 109a which extends perpendicular to the axis of the ram and is located radially inwardly of the cam surface 109. To enable the combination of cam surface 109 and locking surface 109a to be used in the intended manner, the upper sleeve portion 102a is provided with an opening 144 which extends therethrough at a location which, prior to the device being fired, is aligned with the end of the latch 108 remote from the slot in the ram.

The way in which the safety mechanism operates can be seen from Figures 2a, 2b and 2c. When the latch and ram are initially assembled with one another, the latch occupies the position shown in Figure 2a, which is a safety position. Here, the ram-engaging latch portion 108a is acted on by the locking system 109a. Friction forces ensure that the latch remains engaged with the locking surface; typically the ram exerts a force of at least 200N, so the latch is held in a vice-like grip.

Once the device has been assembled, preferably completely, and at least to the extent of the upper sleeve portion 102a being in place, it is cocked by inserting a tool through the opening 144 to push the latch in the direction of the arrow P in Figure 2 into the position shown in Figure 2b (and in Figure 1). In this position the ram-engaging latch portion 108a is in contact with the radially inner end of the cam surface 109. Accordingly,

when the device is actuated as described above it is able to fire, and the latch moves to the position shown in Figure 2c.

CLAIMS:

1. A device for dispensing a material or article, which comprises a spring, which provides an energy store, a dispensing member movable, to effect dispensing, under the force of the spring, latch means having a first position in which it restrains movement of the dispensing member and a second position in which it permits such movement, trigger means operable by the user for moving the latch means from said first position to said second position, and a safety mechanism effective before the device has been completely assembled to prevent movement of the latch means to said second position.

2. A device according to claim 1, wherein the safety mechanism is provided by the latch means having a safety position in which it cannot be moved to the said second position by the trigger.

3. A device according to claim 2, wherein the dispensing member has a pair of latch-engaging surfaces formed therein, the latch means engaging one of the surfaces when in its safety position, and the other of its surfaces when in its said first position.

4. A device according to claim 3, wherein the dispensing member has a slot extending into it from an exterior surface thereof, the slot being defined in part by the said pair of surfaces.

5. A device according to claim 3 or 4, wherein the said one surface is substantially perpendicular to the intended direction of movement of the dispensing member, and the said other surface is inclined to the said direction of movement so that the movement of the dispensing member in the said direction exerts a force on the latch means, when the latch means is in its said first position, urging it

towards its said second position.

6. A device according to any one of claims 2 to 5, having an outer casing surrounding the dispensing member and latch means, the outer casing having an aperture therethrough in the region of the latch means, the aperture providing access to permit insertion of a tool into the interior of the outer casing to move the latch means from its safety position to its said first position.

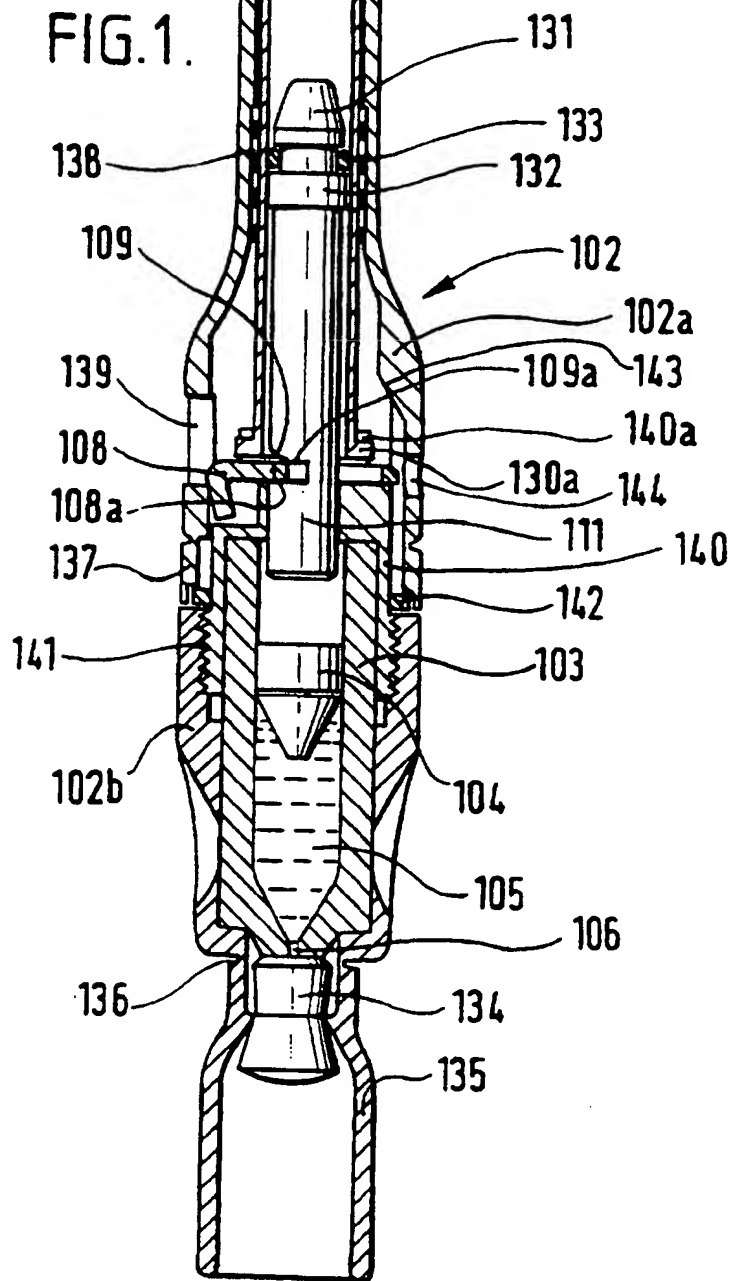
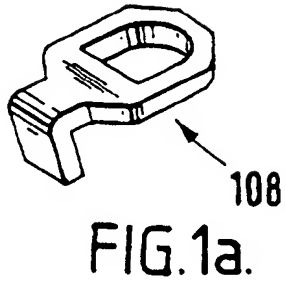
7. A device according to any preceding claim, which is in the form of a needleless injector.

8. A device according to claim 7, comprising a chamber containing a liquid to be injected and provided with an outlet orifice at one end thereof and a piston movable in the chamber to expel the said liquid through the outlet orifice, the dispensing member being spaced from the piston when the latch means is in its said first position and striking the piston to effect movement thereof when the latch means is moved to its said second position.

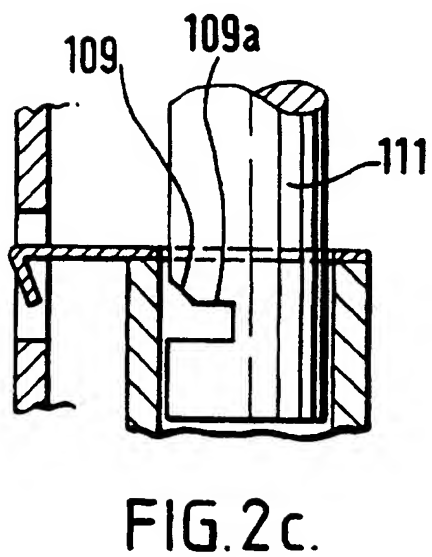
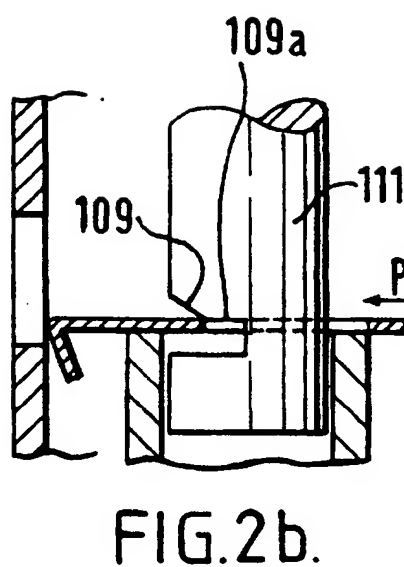
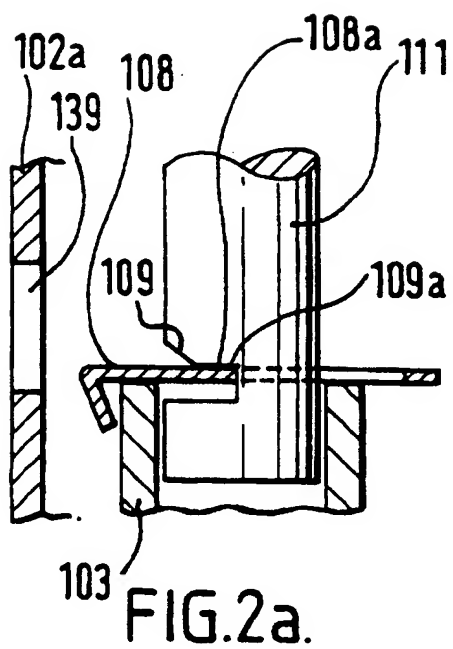
9. A device according to any preceding claim, wherein the spring is a gas spring.

10. A device according to any one of claims 1 to 8, wherein the spring is a mechanical spring.

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INTERNATIONAL SEARCH REPORT

Internat. J. Application No.

PCT/GB 97/00812

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61M5/20 A61M5/30

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 902 279 A (SCHMIDTZ ET AL.) 20 February 1990 see column 6, line 7 - line 15 see column 6, line 25 - line 38 see figures	1
A	---	2
X	CH 518 102 A (GEORG A.HENKE GMBH) 31 January 1972 see column 5, line 56 - column 6, line 14 see figures 2-3C	1
X	US 3 217 712 A (BLUMENSTEIN ET AL.) 16 November 1965 see column 3, line 55 - line 65 see figures 1,3	1
	--- -/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

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INTERNATIONAL SEARCH REPORT

Internal J Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 680 439 A (SUTERMEISTER) 8 June 1954 see column 3, line 37 - line 57 see figure 1 ---	1
A	WO 94 11041 A (R G S.A.S. DI ROSARIA GALLI & C.) 26 May 1994 see page 10, line 7 - line 19 see abstract; figures 1,2 ---	1
A	US 2 653 602 A (SMOOT) 29 September 1953 see column 2, line 42 - line 50 see column 4, line 62 - line 75 see figures 1,2 -----	1,7,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 97/00812

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CH 518102 A	31-01-72	NONE	
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US 2680439 A	08-06-54	NONE	
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		IT 1262288 B	19-06-96
		EP 0768902 A	23-04-97
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US 2653602 A	29-09-53	NONE	